132. (New) The MHC Class II-peptide Complex of claim 132 wherein the MHC binding peptide is covalently attached to the N-terminus of the first polypeptide chain and the Fc domain is covalently attached to the C-terminus of the second polypeptide chain.

133. (New) The MHC Class II-peptide Complex of claim 132 claim 132 wherein the MHC binding peptide is covalently attached to the N-terminus of the second polypeptide chain and the Fc domain is covalently attached to the C-terminus of the first polypeptide chain.

RESPONSE

Claims 1-20 and 103-113 were pending in the Application. In a Response to Restriction Requirement earlier filed on May 7, 2001, Applicants elected with traverse to pursue prosecution of Group III, claims 103 and 114-133. Claims 1-20 are withdrawn, claims 104-113 are canceled, and new claims 114-133 are added by the present Amendment. Upon entry of the present Amendment claims 103 and 114-133 are pending and presented for consideration. Applicants respectfully submit that no new matter is added.

Claim 103 has been amended to recite "coiled-coil" dimerization domains. New claims 114-133 have been added. Support for the new claims may be found in throughout the original specification and in the originally-filed claims.

Rejections Under 35 U.S.C. §112, First Paragraph

Claims 103-113 were rejected under 35 U.S.C. §112, first paragraph, as failing to meet the written description requirement.

In particular, the Office Action suggests that the Specification does not provide support for the recitation "at least an extracellular domain of an MHC Class II alpha chain" and "at least an extracellular domain of an MHC Class II beta chain" as recited in claim 103 and dependent

claims 104-113. These terms do not appear in the currently pending claims and, thus, the rejection is moot.

Accordingly, Applicants respectfully request that the rejections under 35 U.S.C. §112, first paragraph, be reconsidered and withdrawn.

Rejections Under 35 U.S.C. §102(e)

Claims 103-113 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,015,884 issued to Schneck et al. ("Schneck") as evidenced by Janeway et al. (Fundamental Immunobiology, 3rd edition, 1997). The Office Action states that Schneck discloses "divalent MHC peptide complexes which contain at least the extracellular domain of each of the MCH class II chains ... coupled to the dimerization domains of immunoglobulin heavy chain Ch1 constant region, or IgA, IgD, and IgG heavy chains ... and can bind an MHC peptide."

In order to advance prosecution of the "coiled-coil" embodiment of the fusion proteins disclosed in the instant application, all of the claims drawn to the "immunoglobulin" embodiment have been cancelled without prejudice and independent claim 103 has been amended to require that the dimerization domains be coiled-coil dimerization domains.

As stated in the Office Action, Schneck discloses MHC-peptide complexes consisting of Class II chains coupled immunoglobulin molecules wherein an MHC binding peptide is covalently linked to one of the chains. The Specification teaches that the fusion proteins of the invention may be "assembled and secreted even in the absence of a high affinity peptide." (See Examples 3 and 4, pages 55-58.) Thus, unlike Schneck, the claimed fusion proteins do not necessarily include MHC binding peptides. Moreover, the claimed fusion proteins employ coiled-coil dimerization domains. As described on page 32 of the Specification, "coiled-coils are common structural features of dimeric proteins in which two α-helical polypeptides("coils") are twisted ("coiled") about each other to form a larger quaternary structure." Immunoglobulin heavy and light chain domains described in Schneck are not coiled-coil dimerization domains.

The coiled-coiled domains recited in the claims do not require antibody heavy or light chains or MHC binding peptide to generate soluble and functional MHC Class II heterodimers. For at least the forgoing reasons, Applicants submit that Schenck fails to teach or suggest the claimed fusion proteins and, therefore, fails to anticipate pending claims 103 and 114-133.

In light of the foregoing reasons and amendments to claim 103, Applicants respectfully request that the rejections under 35 U.S.C. §102(e) be reconsidered and withdrawn.

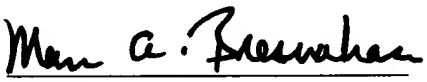
SUMMARY

Upon entry of the present Amendment claims 103 and 114-133 are pending and presented for consideration. Applicants respectfully submit that no new matter is added.

Applicants request that the Examiner reconsider the application and claims in light of the foregoing Amendment and Response, and respectfully submit that the claims, as amended, are in condition for allowance. If, in the Examiner's opinion, a telephonic interview would expedite the favorable prosecution of the present application, the undersigned attorney would welcome the opportunity to discuss any outstanding issues, and to work with the Examiner toward placing the application in condition for allowance.

A petition and fee for a three-month Extension of Time for Response is submitted herewith. Applicants believe that no additional fees are necessitated by the present Amendment. However, in the event that any additional fees are due, the Commissioner is hereby authorized to charge any such fees to Attorney's Deposit Account No. 20-0531.

Respectfully submitted,



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Marked-up Copy of Amended Claim 103

103. (Once Amended) A Class II Major Histocompatibility Complex fusion protein comprising a heterodimer of a first polypeptide chain and a second polypeptide chain;

wherein [said] the first polypeptide chain comprises a fusion of, toward the N-terminus, [at least] an extracellular domain of an MHC Class II α chain and, toward the C-terminus, a first coiled-coil dimerization domain;

wherein [said] the second polypeptide chain comprises a fusion of, toward the N-terminus, [at least] an extracellular domain of an MHC Class II β chain and, toward the C-terminus, a second coiled-coil dimerization domain; and

wherein [said] the first dimerization domain and said second dimerization domain associate in solution at physiological conditions to form a heterodimer capable of selectively binding an MHC binding peptide.